



## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

[Document Identifier: CMS-10511, CMS-10575, and CMS-2552-10]

#### Agency Information Collection Activities: Proposed Collection; Comment Request

**AGENCY:** Centers for Medicare & Medicaid Services.

**ACTION:** Notice.

**SUMMARY:** The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (the PRA), federal agencies are required to publish notice in the Federal Register concerning each proposed collection of information (including each proposed extension or reinstatement of an existing collection of information) and to allow 60 days for public comment on the proposed action. Interested persons are invited to send comments regarding our burden estimates or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

**DATES:** Comments must be received by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

**ADDRESSES:** When commenting, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. Electronically. You may send your comments electronically to <http://www.regulations.gov>. Follow the instructions for "Comment or Submission" or "More Search Options" to find the information collection document(s) that are accepting comments.

2. By regular mail. You may mail written comments to the following address:

CMS, Office of Strategic Operations and Regulatory Affairs

Division of Regulations Development

Attention: Document Identifier/OMB Control Number \_\_\_\_\_

Room C4-26-05

7500 Security Boulevard

Baltimore, Maryland 21244-1850.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' Web Site address at Web Site address at <https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html>
2. E-mail your request, including your address, phone number, OMB number, and CMS document identifier, to [Paperwork@cms.hhs.gov](mailto:Paperwork@cms.hhs.gov).
3. Call the Reports Clearance Office at (410) 786-1326.

**FOR FURTHER INFORMATION CONTACT:** Reports Clearance Office at (410) 786-4669.

**SUPPLEMENTARY INFORMATION:**

Contents

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement and associated materials (see ADDRESSES).

CMS-10511	Medicare Coverage of Items and Services in FDA Investigational Device Exemption Clinical Studies-Revision of Medicare Coverage
CMS-10575	Generic Clearance for the Health Care Payment Learning and Action Network
CMS-2552-10	Hospitals and Health Care Complex Cost Report

Under the PRA (44 U.S.C. 3501-3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term "collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA requires federal agencies to publish a 60-day notice in the Federal Register concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice.

#### Information Collection

1. Type of Information Collection Request: Reinstatement; Title of Information Collection: Medicare Coverage of Items and Services in FDA Investigational Device Exemption Clinical Studies - Revision of Medicare Coverage; Use . Section 1862(m) of the Social Security Act (and regulations at 42 CFR Subpart B (sections 405.201-405.215) allows for payment of the routine costs of care furnished to Medicare beneficiaries in a Category A investigational device exemption (IDE) study and authorizes the Secretary to establish criteria to ensure that Category A IDE trials conform to appropriate scientific and ethical standards. Medicare does not cover the Category A device itself because Category A (Experimental) devices do not satisfy the statutory requirement that Medicare pay for devices determined to be reasonable and necessary. Medicare may cover Category B (Non-

experimental) devices, and associated routine costs of care, if they are considered reasonable and necessary and if all other applicable Medicare coverage requirements are met.

Under the current centralized review process, interested parties (such as study sponsors) that wish to seek Medicare coverage related to Category A or B IDE studies have a centralized point of contact for submission, review and determination of Medicare coverage IDE study requests. In order for CMS (or its designated entity) to determine if the Medicare coverage criteria are met, as described in our regulations, CMS (or its designated entity) must review documents submitted by interested parties or study sponsors. Such information submitted will be a FDA IDE approval letter, IDE study protocol, IRB approval letter, National Clinical Trials (NCT) number, and Supporting materials as needed. Form Number: CMS-10511 (OMB control number: 0938-1250); Frequency: Yearly; Affected Public: Private Sector (Business or other for-profits, Not-for-Profit Institutions); Number of Respondents: 100; Total Annual Responses: 100; Total Annual Hours: 200. (For policy questions regarding this collection contact Cheryl Gilbreath at 410-786-5919.)

2. Type of Information Collection Request: Extension without change of a currently approved collection; Title of Information Collection: Generic Clearance for the Health Care Payment Learning and Action Network; Use: The Center for Medicare and Medicaid Services (CMS), through the Center for Medicare and Medicaid Innovation, develops and tests innovative new payment and service delivery models in accordance with the requirements of section 1115A and in consideration of the opportunities and factors set forth in section 1115A(b)(2) of the Act. To date, CMS has built a portfolio of models (in operation or already announced) that have attracted participation from a broad array of health care providers, states, payers, and other stakeholders. During the development of models, CMS builds on ideas received from stakeholders—consulting with clinical and analytical experts, as well as with representatives of relevant federal and state agencies.

CMS will continue to partner with stakeholders across the health care system to catalyze transformation through the use of alternative payment models. To this end, CMS launched the Health Care Payment Learning and Action Network, an effort to accelerate the transition to alternative payment models, identify best practices in their implementation, collaborate with payers, providers, consumers, purchasers, and other stakeholders, and monitor the adoption of value-based alternative payment models across the health care system. A system wide transition to alternative payment models will strengthen the ability of CMS to implement existing models and design new models that improve quality and decrease costs for CMS beneficiaries.

The information collected from LAN participants will be used by the CMS Innovation Center to potentially inform the design, selection, testing, modification, and expansion of innovative payment and service delivery models in accordance with the requirements of section 1115A, while monitoring the percentage of payments tied to alternative payment models across the U.S. health care system. In addition, the requested information will be made publically available so that LAN participants (payers, providers, consumers, employers, state agencies, and patients) can use the information to inform decision making and better understand market dynamics in relation to alternative payment models. Form Number: CMS–10575 (OMB control number: 0938–1297); Frequency: Occasionally; Affected Public: Individuals; Private Sector (Business or other For-profit and Not-for-profit institutions), State, Local and Tribal Governments; Number of Respondents: 30,110; Total Annual Responses: 23,110; Total Annual Hours: 25,917. (For policy questions regarding this collection contact Dustin Allison at 410-786-8830.)

3. Type of Information Collection Request: Extension of a currently approved collection; Title of Information Collection: Hospitals and Health Care Complex Cost Report; Use: Under the authority of sections 1815(a) and 1833(e) of the Act, CMS requires that providers of services

participating in the Medicare program submit information to determine costs for health care services rendered to Medicare beneficiaries. CMS requires that providers follow reasonable cost principles under 1861(v)(1)(A) of the Act when completing the Medicare cost report. Under the regulations at 42 CFR 413.20 and 413.24, CMS defines adequate cost data and requires cost reports from providers on an annual basis. The Form CMS-2552-10 cost report is needed to determine a provider's reasonable cost incurred in furnishing medical services to Medicare beneficiaries and calculate the hospital settlement amounts. These providers, paid under the inpatient prospective payment system (IPPS) and the outpatient prospective payment system (OPPS), may receive reimbursement outside of the PPS for hospital-specific adjustments such as Medicare reimbursable bad debts, disproportionate share, uncompensated care, direct and indirect medical education costs, and organ acquisition costs. The Form CMS-2552-10 cost report is also used for rate setting and payment refinement activities, including developing a hospital market basket. Additionally, the Medicare Payment Advisory Commission (MedPAC) uses the hospital cost report data to calculate Medicare margins, to formulate recommendations to Congress regarding the IPPS and OPPS, and to conduct additional analysis of the IPPS and OPPS. Form Number: CMS-2552-10 (OMB control number: 0938-0050); Frequency: Yearly; Affected Public: Private Sector (Business or other For-profit and Not-for-profit institutions), State, Local and Tribal Governments, Federal Government; Number of Respondents: 6,088; Total Annual Responses: 6,088; Total Annual Hours: 4,097,224. (For policy questions regarding this collection contact Gail Duncan at 410-786-7278.)

Dated: November 15, 2018.

**William N. Parham, III,**

*Director, Paperwork Reduction Staff,*

*Office of Strategic Operations and Regulatory Affairs.*

Billing Code: 4120-01-U-P

[FR Doc. 2018-25312 Filed: 11/19/2018 8:45 am; Publication Date: 11/20/2018]